

**Amendments to the Claims:** This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. - 12. (Cancelled)

13. (Withdrawn) A method to obtain an immunotherapeutic agent that contains cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain of cells comprising the sequential steps of

- a) culturing the cells for a period of at least three weeks and
- b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds.

14. (Withdrawn) The method according to claim 13 wherein the cell culturing period ranges from 3 to 4 weeks.

15. (Withdrawn) The method according to claim 13 wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.

16. (Withdrawn) The method according to claim 15 wherein the non-ionic surfactant is an octylphenol ethoxylate compound.

17. (Withdrawn) The method according to claim 16 wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.

18. (Withdrawn) The method according to claim 13 wherein the cells are homogenized in a buffered medium having a neutral pH.

19. (Withdrawn) The method according to claim 18 wherein the medium is buffered with PBS buffer.

20. (Cancelled)

21. (Withdrawn) The method according to claim 13 further comprising the steps of

- c) centrifuging the homogenized cell mixture to separate the cell wall fragments from the non-fragmented cells and the solubilized cell compounds,
  - d) washing the cell wall fragments and further treating the cell wall fragments to inactivate any remaining virulent cells, and
  - e) lyophilizing the resulting immunotherapeutic agent.
22. (Withdrawn) The method according to claim 21 wherein the cell culturing period ranges from 3 to 4 weeks.
23. (Withdrawn) The method according to claim 21 wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
24. (Withdrawn) The method according to claim 23 wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
25. (Withdrawn) The method according to claim 24 wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
26. (Withdrawn) The method according to claim 21 wherein the cells are homogenized in a buffered medium having a neutral pH.
27. (Withdrawn) The method according to claim 26 wherein the medium is buffered with PBS buffer.
- 28.-34. (Cancelled)
35. (Withdrawn) A method for the combined treatment of tuberculosis comprising administering the immunotherapeutic agent of claim 20 in combination with at least one drug suitable for the treatment of tuberculosis.
36. (Withdrawn) The method of claim 35 wherein the combined therapy is sequential or simultaneous.
37. (Withdrawn) The method of claim 35, wherein the drug is selected from the group consisting of isoniazid, rifampicin, and combinations thereof.

38.-43. (Cancelled)

44. (Withdrawn) A method for the combined treatment of tuberculosis comprising administering the immunotherapeutic agent of claim 28 in combination with at least one drug suitable for the treatment of tuberculosis.

45. (Withdrawn) The method of claim 44 wherein the combined therapy is sequential or simultaneous.

46. (Withdrawn) The method of claim 44, wherein the drug is selected from the group consisting of isoniazid, rifampicin, and combinations thereof.

47. (Currently Amended) An immunotherapeutic agent comprising cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain of cells obtained by a process ~~comprising~~consisting essentially of the steps of:

- a) culturing the cells for a period of at least three weeks,
- b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds, wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters,
- c) centrifuging the homogenate to separate the cell wall fragments from the non-fragmented cells and the solubilized cell compounds, and
- d) washing the cell wall fragments and further inactivating any remaining virulent cells to obtain the immunotherapeutic agent, and
- e) optionally, lyophilizing the immunotherapeutic agent;

wherein the immunotherapeutic agent is substantially free of non-fragmented cells and solubilized cell compounds.

48. (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the cell culturing period ranges from 3 to 4 weeks.

49. (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
50. (Previously Presented) The immunotherapeutic agent according to claim 49, wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
51. (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the cells are homogenized in a buffered medium having a neutral pH.
52. (Previously Presented) The immunotherapeutic agent according to claim 51, wherein the medium is buffered with PBS buffer.
53. (Cancelled)
54. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 47.
55. (Currently Amended) A pharmaceutical composition comprising the immunotherapeutic agent of claim ~~53~~47, wherein the immunotherapeutic agent has been lyophilized.
56. (Previously Presented) The pharmaceutical composition according to claim 54, in the form of liposomes.
57. (Previously Presented) The pharmaceutical composition according to claim 56, wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.
58. (Previously Presented) The pharmaceutical composition according to claim 57, wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.
59. (Previously Presented) The pharmaceutical composition according to claim 58, wherein the sterols are selected from cholesterol and biliar salts.
60. (Previously Presented) The pharmaceutical composition according to claim 59, further comprising vitamin E.